

FIG. 1

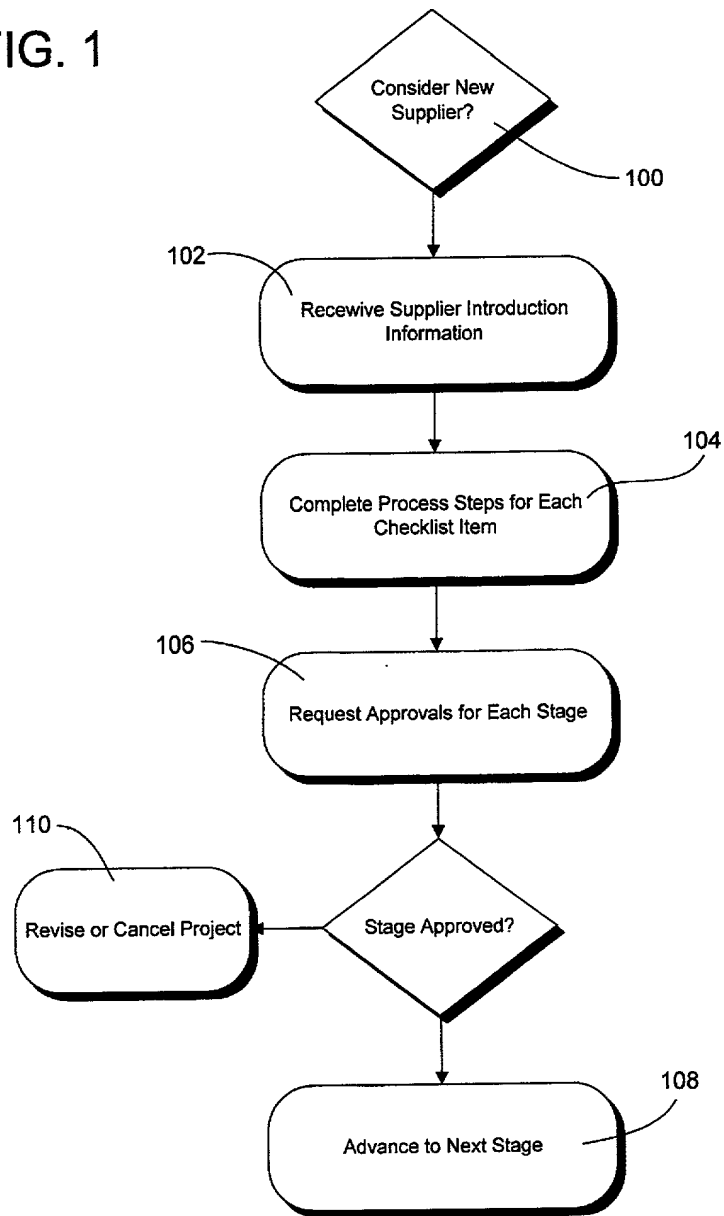
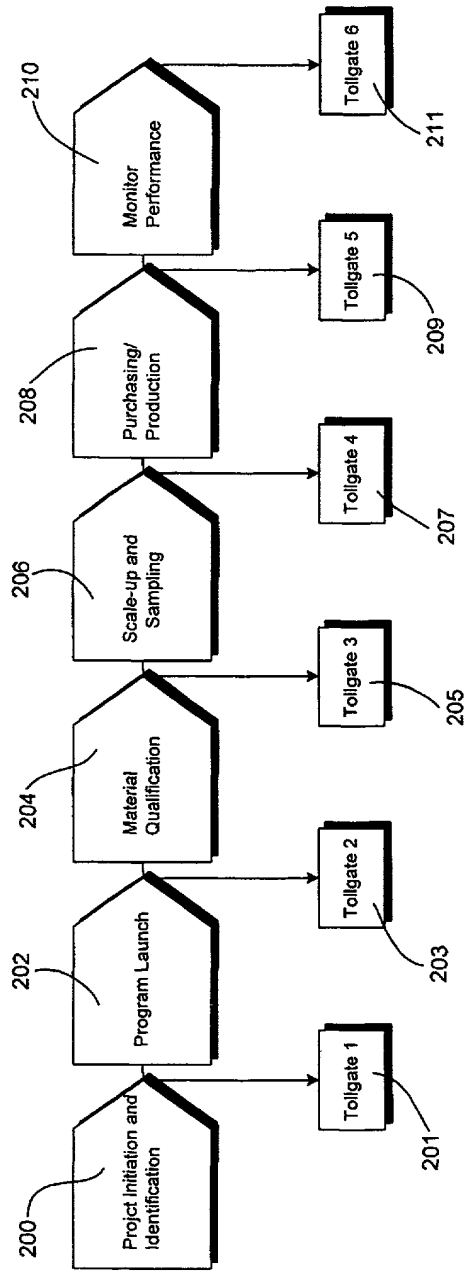


FIG. 2



Stage 1 Global	
	Identify Potential Suppliers
	What are the names of the potential suppliers?
	Is there a priority ranking at this point?
	If so, on what basis?
	Initiate Global Specification Process
	Does an active global specification currently exist?
	Does a pending global specification currently exist?
	Are there plans to activate the global specification?
	Does a global specification need to be initiated?
	Whose responsibility will it be?
	Expected Timing?
	EHS Preliminary Analysis
	- Has the Nature of Supply form been filled out and submitted to EHS?
	- Has the form been reviewed and has EHS assigned a preliminary rating?
	- What further follow steps are required at this point?

FIG. 3

Stage 1 Global/ Site	
	Which site will be the lead site for qualification?
	Has the financial analysis with expected savings been completed?
	Has an Opportunity/Difficulty Analysis been completed?
	Is the lead site committed to moving forward with the project
	after reviewing both the projected benefits and degree of difficulty?
	Does a QPID Number exist for this program?
	Are the benefits allocated in QPID?
	If not who will be responsible for creating one and/or allocating benefits?
	Packaging Plan
	- What packaging types does the site need (e.g. bags, supersacks, truckload, railcar, etc.)?
	- What packaging types can the new supplier provide? If so, what are they?
	- Are there particular CTQs around packaging such as: labeling; package material type; package size; package dimensions, etc.
	- Are there particular Logistics CTQs such as: Port of Entry; stacking height of pallets, etc.
	- Where does GEP take ownership of the material?
	- If GEP takes ownership after entry into the USA, can the new supplier make a customs entry without organization assistance?

FIG. 4

Stage 1 Site MOC	
	Business Review
	- Has the lead site reviewed the global inputs and made a commitment of resources to move forward with qualification of the new supplier/material?
	Application Assessment
	- Will the supplier change affect the customer?
	- Are there multiple customers?
	- Global Customers?
	- Who is most critical?
	- What volume is affected?
	- Degree of Difficulty
	Market and Business Plan
	- What is the proposed change? Be specific.
	- What are the primary motivations for it?
	- What products and/or processes are impacted?
	- Identify external customers affected.
	- Identify internal customers affected.
	- What is the probability that the change will result in a change in product for external customers?
	- Has the change been communicated to the commercial team?
	- What was the documented commercial team feedback?
	- Establish timing.
	Customer CTQs
	- Have the CTQs for the raw material been defined?
	- Is the site using the global specification?
	- To what extent are the customer CTQs at risk by making the change?
	- Are there any current outstanding issues where the raw material is a suspected cause?
	- What have been the most common customer issues related to this particular raw material in the past?
	- How will this change in supplier affect them?
	Risk Assessment
	- What are the potential external benefits of the change?
	- What are the potential internal benefits of the change?
	- What are the potential internal and external risks? Be specific.
	MGAP
	- Does an MGAP exist?
	- Is this raw material expected to play a part in future products?

FIG. 5

Stage 2 Global	
Supplier Assessment and Selection	
	- Has the 6 Sigma Supplier Selection Wizard been filled out for the incumbent and new supplier?
	- Are there any issues with the new supplier based on the data provided such as concerns with financial stability, capacities, quality & consistency, or ability to export successfully to GEP sites?
	- Is DMAIC or Supplier Development recommended?
	- What other concerns should be addressed based on the data?
	- Should the team move forward with qualification based on the overall assessment vs. the incumbent supplier?
EHS Questionnaire	
	- Was an EHS questionnaire required by EHS for the new supplier?
	- If so, has it been filled out and returned to EHS?
	- Has EHS reviewed the questionnaire?
	- What follow-up actions are required per EHS at this time?
Food/Medical/Toy Evaluation	
	- Does this material have to be compliant with food/medical/toy regulations anywhere on the globe?
	- If so, where?
	- Has the supplier been advised of the compliance regulations?
	- Has the supplier agreed to meet the compliance regulations?
	- Does the supplier need to initiate any testing to demonstrate compliance prior to GEP production trials?
	- Does the supplier know what testing is required and where and how to get it done?
	- When will the supplier initiate testing (e.g. prior to or after technology testing is completed)
Sample to Supplier	
	- Was a sample of the Global Standard sent to the supplier after the Cpk data required by the Wizard was obtained?
Transportation & Customs Clearance	
	- Is the supplier or an affiliate organization set up with Customs as an importer of record with their own Tax Identification Number and surety bond so that they can make a customs entry (Import) without the assistance of GEP in the country of destination?
	- If the answer to question #1 is Yes, can they provide the material to our plant location(s) Delivery Duty Paid?
	- If they cannot complete the entry process into the country of delivery, are they able to make the goods available at our plant location(s) in the country of importation on a DDU basis?
	- If you cannot complete the entry process and cannot deliver the goods to our plant location(s) are you able to make the goods available at the named port of entry in the country of importation on a CIF basis?
	- If we purchase from them on a DDU or CIF basis are they willing to reveal the actual freight charges for deliveries into the US so that we can comply with US Customs regulations?
	- Is the supplier willing to authorize the steamship lines to release the rate level?
	- If the manufacturing is located in a GSP country as defined by US Customs, are they willing to work with GEP to determine whether their product is eligible for GSP reduced or free duty?
	- If they sell to GEP on a DDP basis are they willing to provide copies of their import entry documents to GEP's third party duty drawback provider?
	- Is this a Hazardous material for Transportation purposes?
	- If this is a Hazardous material for Transportation purposes, are they knowledgeable about the international transportation requirements for Hazardous materials for Transportation?

FIG. 6

Stage 2 Global/Site	
	Translation Process
	- What other sites use this material?
	- What are the potential benefits for those sites to translate this qualification (e.g. cost out, quality)?
	- Who are the stakeholders who will help with translation?
	- Is there a plan in place to take the lead site's data to facilitate the translation of the qualification?
	- Is there commitment from the translation sites to translate?
	Stakeholder Analysis
	- Who are the functional stakeholders from the lead site?
	- Who are the functional stakeholders from the other sites that should be involved?
	- Who are the functional stakeholders from other businesses that should be involved?
	Project Letter
	- Has a letter of intent which states our desire to purchase material at a set price and/or set volume been signed and sent to the new supplier to lock in a tentative agreement?
	- Are both parties in agreement to the tentative terms?
	Supplier MSDS
	- Has an MSDS from the new supplier been received?
	- Have Product Stewardship & EHS reviewed the MSDS?
	- Have Product Stewardship & EHS approved the MSDS?
	- Has the MSDS been scanned into electronic form for easy distribution to all interested parties?
	Product Stewardship Questionnaire
	- Has the Product Stewardship Questionnaire been sent to the new supplier?
	- Has the supplier filled out and returned the questionnaire?
	- Has EHS reviewed the questionnaire?
	- Are there any issues which need to be resolved?
	- If so, do they preclude moving to the next phase and tollgate before being addressed?

FIG. 7

Stage 2 Site MOC	
Cross Functional Team/Leader	
- Functional members	
- Global members	
- Have Commercial, Sourcing, Materials, Manufacturing, Quality, Finance, Technology, EHS, Product Stewardship, Legal, Maintenance, and HR representation been considered?	
- Are PPDC resources needed?	
- How will functions that are not actively participating on the team be communicated with?	
Verify and Freeze CTQ	
- Production/performance	
- Secondary operations (i.e., paintability)	
- Processing (dust, pellet cuts, etc.)	
- Quality related CTQ (be specific)	
- Appearance (color surface)	
- Other (e.g., packaging, regrind, use, etc.)	
- Do the CTQ's include measure of product stability (e.g., thermal)?	
QFD Performed	
- Has a QFD been performed?	
- Have the external CTQ's been internalized through a QFD?	
- What are the internal CTQ's not tied directly to an external one (e.g., yield, container, etc.)?	
- Can we test for all CTQ's?	
MGP & PP	
- Is there an MGP and PP?	
- Is it up to date?	
- Are the change(s) going to affect the MGP & PP?	
- Is a new product request (NPR) needed?	
- Has a new Technology plan been defined?	
- Does a product exist in another geography?	
Project Timeline and Resourcing Plan	
- Create resource plan and delineate timeline	
- Define critical milestone in plan	
- Verify fit with market and business timing needs	
- Identify preliminary investment needs	
- Define preliminary equipment needs and location of manufacture	
- Is an AR needed? Is the investment budgeted?	
Target Cost	
- Cost assumption (standard and actual)	
- Is cost of special CTQ's captured?	
- Verified by Finance?	
Project Risk Assessment	
- How big is this change relative to current practice?	
- Is it a global change?	
- Does it cross product lines? Who will coordinate with other product lines?	
- How many grades are affected per product line?	
- Are these similar grades with similar CTQ's?	
- What agency approvals exist and/or are required (UL, NSF, FDA, etc.)?	
- Conduct risk analysis including regulatory, quality, manufacturability EHS, policy threats	
- Which CTQ's are at greatest risk to be changed?	
- How might the change adversely affect manufacturability?	
- What legal risks (liability, freedom to practice) need to be evaluated?	
- Are there raw materials sourcing risks that need to be evaluated?	
- Does the specification of the new raw materials match that of the old one?	
- What EHS risks are there (exposure, emissions, ergonomic)?	
- Can the difference in specification affect certain CTQ's?	
- Can the difference in specification affect EHS permit.	
- Is NMI required?	
- Is PMN required?	
- Is the new material/product compatible if mixed with the old material/product?	
- Do we have a disposal plan of the old material?	
- Where in the plant do we plan to do the change? Are changes to the plant hardware required?	
- What is the order of magnitude investment required?	
- What are the operating cost ramifications of the change?	
- Are there risks in terms of project timing? Do the benefits of this change outweigh the risks?	
- Are there customer "No Change" clauses? If yes, list the customers	
- Are any customer certifications affected or jeopardized?	
- If yes, list the customers and the certification parameters impacted	
- Silent change or notify customers	
Competitive Assessment	
- How is the change going to affect our competitive position?	
- Has a thorough competitive assessment been done?	
- Is it documented?	

FIG. 8

Stage 3 Global	
	Validate Test Methods
	- Are new supplier test methods different than incumbent suppliers?
	- Has the new supplier provided us with copies of their test methods?
	- Are the new supplier's test methods based upon published third party test methods such as ASTM, ISO, AOCS, etc. If so, which one(s)?
	- Are correlation studies needed to validate methods?
	* If so, have they been successfully completed?
	- What is the % agreement between organization's and the new supplier's test methods?
	- Has the new supplier done a GRR on their methods?
	* If they have, what is the %GRR for each method?
	* If not, are GRRs planned?
	Resolve Specification
	- Is the supplier capable of testing all specification parameters?
	- Does the new supplier's product meet all specification parameters?
	* If such data does not exist, can we generate it?
	* Should we establish new data based specification limits?
	- Is the specification a global specification?
	- Has a global specification been initiated?
	- Will the global specification be necessary for qualification?
	- What is the timing for the completion of the global specification?
	- Has the global specification been implemented?
	On Site(s) Assessment of Supplier
	- Has a GEP representative visited the site(s) and filled out the EHS observational checklist?
	* Has the checklist been reviewed by EHS?
	* If yes, who reviewed it?
	* Are there any issues or follow-up actions?
	- Has an organization leader visited the supplier's manufacturing site(s)?
	* If yes, who visited? What were their comments?
	- Are there any issues with the site(s) that require resolution prior to proceeding with the qualification?
	* Are the issues severe enough to terminate qualification?
	* Who needs to be involved in the resolution?
	* What is the timeline for the resolution process?

FIG. 9

Stage 3 Global/Site	
	Analytical and Lab Test Validation
	- Have the equivalencies of materials been established via analytical testing?
	* Are the impurity levels and profiles similar?
	- Are there any issues?
	* Are they severe enough to terminate the qualification?
	- Has the material been tested for each CTQ in the intended products and/or applications?
	* Do the test results support qualification?
	Complete Food/Medical/Toy Compliance Testing
	- If food contact compliance is required, has the new supplier provided a letter from their product stewardship team stating what regulatory agencies their product is compliant with (e.g. FDA, BgVV, French Positive List, JHOSPA, etc)?
	- Is further testing required by Product Stewardship for the material?
	- If so, has the supplier submitted materials to a certified lab for the appropriate testing (e.g. metals, PCB, and amine testing)?
	* Do the results support approval for food contact applications?
	* Are there any restrictions on food contact applications such as loading levels, grade restrictions, etc.?

FIG. 10

Stage 3 Site MOC	
	Verify and Test CTQ's
	- Does product meet all CTQ's on lab scale when new supplier's raw material is used? (e.g., Product/Performance; Secondary Operations; Processing; Quality; Appearance (color/surface); etc.)
	- Property Test Methods Exist
	- Gauge R&R on test for CTQ's (tech., QA)
	Product, Application, Process Risk Management, EHS, FMEA
	- Have existing FMEA's been reviewed?
	- If an FMEA doesn't exist, should one be performed?
	- Have potential problems been identified through brainstorming?
	- What EHS/regulatory permits, controls and registration are required?
	Freedom to Practice
	- Are there any patents that blocks us?
	* Is the patent search complete?
	- What is useful or novel that we should patent?
	- Liability review (product, process)
	Formulation and Process Tolerancing
	- Develop experimental plan
	- Does the plan include the grade made for the toughest customer?
	- Does it include multiple grades?
	- Does it address secondary processing and non-property CTQ's?
	- Develop new test methods as appropriate (lab/pilot)
	- Conduct screening experiments (lab/pilot)
	- Define process or products tolerancing windows
	- List potential manufacturing issues
	- Are they addressed in the experimental plan:
	- Based on screening and optimization experiments, what is the impact on the CTQs?
	- How might the customer be affected by shifts in product properties (or non-property factors) that fall within specification ranges?
	- Will the customer be notified of the change?
	- Notification plan (who will do it? When? How?)
	Raw Materials
	- What raw materials analysis and evaluations are needed?
	- Raw material CTQ defined?
	- Raw material NMI initiated?
	- How many lots of the raw material are being tested?
	- Sourcing plan
	- Raw material availability?
	- Has raw material packaging been considered?
	Manufacturing Plan
	- What is the manufacturing plan?
	- Has the impact of the change on manufacturability been assessed experimentally? What were the findings?
	- If needed, has the AR been approved?
	- What existing equipment is being used?
	- What new equipment is being installed?
	- Process support for scale-up identified?
	- What other products are produced on the same equipment?
	- Has the change been communicated to those responsible for other products that might be affected.
	Field Quality Plan
	- Customer sampling plan defined?
	- Who will get the customer feedback?

FIG. 11

Stage 4 Global	
	Finalize Global Specification
	- Has the global specification been implemented?
	- What issues, if any remain?
	* What is the plan and timeline for resolution?
	Mutually Agreed Upon Specification (MAUS)
	- Has a specification been sent to the supplier to sign?
	- Has the supplier signed the specification?
	- Are there any issues for getting the specification signed?
	* What is the plan and timeline for resolving the issues?
	Finalize Plan for Packaging & Logistics
	- Have the sites approved and the supplier agreed to the packaging plan?
	- What packaging issues if any remain?
	* What is the plan and timeline for resolving the issues?
	- Have the supply routes been mapped out for each site?
	- Are there any issues or concerns with the delivery logistics?
	* What is the plan and timeline for resolving the issues?
	* Refer back to stage 2 transportation and customs clearance questions to see if all outstanding issues are resolved. Are they?

FIG. 12

Stage 4 Site MOC	
	Verify and Test CTQ's
	- What is the manufacturing trial plan? Will it adequately address the CTQ's?
	- Have EHS & Safety MOC reviews been completed to prepare for trials?
	- Is the documentation related to these reviews easily accessible? Who has them?
	- Has there been adequate training in preparation for the trial?
	- What is the disposition plan for the trial material?
	- Product performance meets all CTQ's on scale-up? (i.e., properties demonstrated; secondary operations; processing checklist executed; quality; appearance (color, surface), etc.)
	- Are there shifts in properties within the specification ranges which might impact the customer?
	- QA test methods calibrated/capable (<25%)?
	- Customer sampling:
	* Which customers will evaluate the product(s)?
	* How will the feedback be obtained?
	* MSDS Complete
	Agency Approval
	- Has the new material received all appropriate agency approvals such as FDA, French Positive List, JHOSPA, etc.?
	Documented Customer Feedback and Acceptance
	- All product CTQ's met?
	- Processing and secondary operations verified?
	- Documentation?
	- Multiple Customer/trial verification
	Manufacturing Process and Specification Freeze
	- Process control plan for commercial scale-up
	- Process FMEA complete, high RPNs addressed
	- Raw material available/specifications in place?
	- Acceptance yield/rate demonstrated?
	- Material handling/packaging capability
	- Hazard review completed?
	- Cost targets still on track?
	- Are all process modifications complete?
	- Have all EHS approvals been obtained?
	- Are MSDS sheets updated?
	- Have patents applications been filed?
	- Has the gage R&R of QA tests been established?
	- Have the risk/benefit analysis and cost ramification of the change been revisited?

FIG. 13

Stage 5 Global/Site	
	Complete Translation to Other Sites/Businesses
	- What other sites/businesses can this be translated to?
	- Have they received communication that the lead site has qualified the material?
	* Who will send the communication? When?
	- Has all necessary information been received that will be required for translation?
	* If not, when will it become available?
	Finalize and Sign Contract
	- Has the contract been signed with the new supplier?
	* Are there any issues with getting the contract finalized?
	* If so, what are they?
	* What is the plan and timeline for resolving the issues?
	- Has a copy of the contract been sent to the purchasing sites?
	Finalize Inventory and Logistics Plans
	- Has the incumbent supplier's inventory of material been reviewed?
	- What is the site's plan for sourcing this material?
	- Are all transportation routes established?
	- Are there any potential customs issues?
	* What is the plan and timeline for resolution or prevention of these issues?
	Submit Purchase Orders for Production Quantities
	- Has the first commercial purchase order been submitted?
	- When will material arrive?

FIG. 14

Stage 5 Site MOC	
	Proven Manufacturing Capability
	- 10 lots demonstrated to meet CTQ's?
	Control and Audit Plan
	- Ten (10) lots demonstrated 4.5 sigma capability?
	- What CTQ's will be tracked during Mfg. and for how long?
	- Is the change reflected in the Mfg. Control Plan?
	- Are the SOP's completed?
	- Is training complete?
	- Has an inventory control plan been established?
	FMEAs Revisited
	- FMEA's updated, high RPNs addressed?
	Commercialization Package and Communication
	- Do all stakeholders understand the change, its ramification and timing
	- Does the Business Team or Product Core Team understand the benefits and remaining risks of the change and endorse it?
	- Is a commercial communication plan in place?
	- Is there a plan in place to get feedback from the field on product performance following the change?

FIG. 15

Stage 6 Site MOC	
	Manufacturing Capability Audit
	- Has the tracking data been analyzed?
	- How has the change affected our ability to meet the customer CTQ's (post-change DPMO)?
	- What is our ability to consistently meet the customer CTQs (post-change DPMO)?
	- Have there been any manufacturability issues (e.g., yield, operability, EHS) and root cause identified?
	- Is the rework plan functioning effectively?
	Field Performance
	- How are affected products performing for the customer (internal or external)?
	- How is the product performing in secondary operations?
	- Has there been a significant change in the number of customer complaints for affected grades?
	- Has there been a significant change in the types of complaints?
	Results Versus Plan
	- How do the results of the change compare to the plan (e.g., yield vs. Target, productivity vs. Goal)?
	- Should the tracking period be extended based on the initial results?
	- Has the control plan been revisited and finalized?
	- Have SOP's been updated based on initial manufacturing experience?
	- What is the plan to audit performance going forward?
	- Has the change been fully documented?
	- Have equipment drawings and maintenance records been updated?
	Rationalization Plan
	- Have obsolete products and raw materials been purged from inventory?
	- Is there a rationalization plan in place if needed?

FIG. 16